Media Release

Basel, 3 July 2013

FDA grants Roche’s obinutuzumab (GA101) Priority Review for previously untreated chronic lymphocytic leukemia (CLL)

- Announcement follows FDA Breakthrough Therapy Designation for GA101 in CLL
- FDA decision on the GA101 Biologics License Application (BLA) is expected by the end of 2013

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company’s Biologics License Application (BLA) for obinutuzumab (GA101) and granted Priority Review for GA101 in the treatment of chronic lymphocytic leukemia (CLL), one of the most common forms of blood cancer, based on final stage 1 data from the pivotal CLL11 trial. The FDA confirmed the action date is December 20, 2013. This acceptance follows the GA101 FDA Breakthrough Therapy Designation that was received in May 2013.

“We’re excited that the FDA has granted GA101 in CLL both Breakthrough Therapy Designation and Priority Review,” said Hal Barron, M.D., chief medical officer and head, Global Product Development. “These FDA designations acknowledge the promising trial results with GA101 and will hopefully allow this novel medicine to reach the people who need it in an expedited time frame.”

The FDA is evaluating data from the pivotal Phase III CLL11 trial, which found that GA101 demonstrated a statistically significant 86 percent reduction in the risk of disease worsening or death (HR=0.14, 95 percent CI 0.09-0.21, p<0.0001) when combined with chlorambucil compared to chlorambucil alone in previously untreated people with CLL and co-existing medical conditions. In CLL11, no new safety signals were detected for GA101. The most common Grade 3-4 adverse events (AEs) for GA101 were infusion-related reactions (IRRs) and low cell count of certain white blood cells (neutropenia) which did not result in an increased risk of infection. The incidence and severity of IRRs decreased after the first infusion and no Grade 3-4 IRRs have been reported beyond the first infusion.

Marketing applications have also been submitted to other regulatory authorities, including the European Medicines Association (EMA) in April 2013.
About GA101

GA101 is an investigational medicine designed to attack cells that have a certain marker on their surface. It kills targeted cells both directly and together with the body’s immune system. GA101 is currently being investigated in a large clinical program, including multiple head-to-head Phase III studies versus rituximab in indolent non-Hodgkin’s lymphoma (NHL) and diffuse large B-cell lymphoma (DLBCL).

About Chronic Lymphocytic Leukemia (CLL)

CLL is one of the most common forms of blood cancer and in 2013, it is expected that there will be nearly 5,000 deaths from CLL in the United States.

About FDA Breakthrough Therapy Designation

FDA ‘Breakthrough Therapy Designation’ is designed to expedite the development and review of medicines intended to treat serious and life-threatening diseases and to help ensure people have access to them through FDA approval with a shorter review time.

About Roche in hematology

For more than 20 years, Roche has been developing medicines that redefine treatment in hematology. Today, we’re investing more than ever in our effort to bring innovative treatment options to people with cancers of the blood.

In addition to GA101, Roche’s pipeline of potential hematology medicines includes two antibody-drug conjugates (anti-CD79b [RG7596] and anti-CD22 [RG7593]), a small molecule antagonist of MDM2 (RG7112) and in collaboration with AbbVie, a small molecule BCL-2 inhibitor (RG7601/GDC-0199).

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche
Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Relations
Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Štěpán Kráčala